

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference Le A 32 701-PC Bu | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/EP99/03392 | International filing date (day/month/year) 17/05/1999 | Priority date (day/month/year) 28/05/1998 |
| International Patent Classification (IPC) or national classification and IPC C07K16/00 | | |
| Applicant BAYER AKTIENGESELLSCHAFT et al. | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of ⁴(3) sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

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| Date of submission of the demand 19/11/1999 | Date of completion of this report 16.02.2000 |
| Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | Authorized officer Mennessier, T Telephone No. +49 89 2399 8687  |

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/EP99/03392

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-33,35-40 as originally filed

Claims, No.:

1-5 as originally filed

Drawings, No.:

1-4 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | |
|-------------------------------|-----------------|
| Novelty (N) | Yes: Claims 1-5 |
| | No: Claims |
| Inventive step (IS) | Yes: Claims 1-5 |
| | No: Claims |
| Industrial applicability (IA) | Yes: Claims 1-5 |
| | No: Claims |

2. Citations and explanations

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/EP99/03392

1. Comments with respect to item I

There appears to be no page 34 being part of the description. Indeed, the only page 34 of the file is the sheet with the claims.

Page 35 is that page which briefly describes the figures in the drawings.

Pages 36-40 correspond to the sequence listing filed as being part of the original description (see Box No. VIII of the PCT Request).

2. Comments with respect to item V

- a) A monoclonal antibody as defined in either of claims 1 and 3 appears not to be disclosed in the relevant state of the art (see the international search report). Therefore, the claimed subject-matter as a whole can be regarded as new, in accordance with the requirements of Article 33(2) PCT.
- b) It can be considered that the invention has solved in a non-obvious way the technical problem posed by the preparation of monoclonal antibodies that allow the sensitive detection of native PIINP from patient samples. The preparation of monoclonal antibodies directed against an epitope within the 30-most N-terminal amino acids of human PIINP (see claims 1-2) or of a monoclonal antibody as defined in claim 3 is not suggested by the relevant state of the art. Nor is the use of such an antibody in an immunoassay in combination with an antibody as defined in claim 3 (see claim 4) or an antibody directed against PIINP that specifically detects trimeric PIINP (see claim 5). Therefore, it can be acknowledged that the claimed subject-matter as a whole involves an inventive step, in accordance with the requirements of Article 33(3) PCT.